

## REMARKS

Claims 1-20 are pending. Claims 1, 12, 14, and 20 have been amended.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### I. The Rejection of Claims 1-20 under 35 U.S.C. 112 (Indefinite)

Claims 1-20 are rejected under 35 U.S.C. 112 as allegedly indefinite. The Examiner alleges that the recitation "an environmental pool of microorganisms" is not clear. The Examiner states that although the specification uses this term with regard to a few types of samples, the specification does not provide a definition for this term. The Examiner states it is unclear whether this term encompasses samples that also include organisms or cells that are not microorganisms or does this term encompass samples that only contain microorganisms.

The term "microorganism" is used in the specification according to its very well known art recognized meaning to refer to single-celled organisms such as bacteria and fungi. Thus, "microorganisms" are a species of organisms. The phrase "an environmental pool of microorganisms" means an environmental sample which comprises microorganisms. The claims do not exclude the presence of other organisms, but require the presence of microorganisms. However, in order to expedite prosecution, the claims have been amended to recite "comprising microorganisms."

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

### II. The Rejection of Claim 20 under 35 U.S.C. 112 (Indefinite)

Claim 20 is rejected under 35 U.S.C. 112 as allegedly indefinite. The Examiner alleges that the phrase "the polypeptide with an activity of interest" lacks antecedent basis.

The claims are amended to delete "with an activity." Accordingly, it is respectfully submitted that this rejection is rendered moot as there is proper antecedent basis for the phrase "polypeptide of interest."

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

### III. The Rejection of Claims 1-3, 5-6, 8-9, 12-17 and 20 under 35 U.S.C. 102

Claims 1-3, 5-6, 8-9, 12-17 and 20 are rejected under 35 U.S.C. 102(b) as anticipated by Okuta et al. This rejection is respectfully traversed.

Foremost, the Examiner alleges that Okuta et al. is prior art under 35 U.S.C. 102(b) because the provisional application of the instant application does not disclose the claimed invention. In particular, the Examiner alleges that the provisional application "never refers to an '*environmental pool of microorganism*' as set forth in the instant claims, and therefore does not provide basis for the type of environmental samples now encompassed by the claims."

Applicants respectfully disagree. US Provisional application (60/106,319) and Danish priority application (1998 01388) (which have identical disclosures) both clearly provide support for the claimed invention. US Provisional application 60/106,319 discloses on page 5 (emphasis added), that:

The environmental pool of organisms containing DNA encoding a polypeptide with an activity of interest are typically microorganisms such as Eubacteria, Archaeobacteria, fungi, algae and protozoa.

Applicants also direct the Examiner to original claims 12-14 of the priority application in which these claims clearly recite that the "environmental pool of organisms comprises microorganisms." Claims 1 and 12-14 of the US Provisional application (60/106,319) are reproduced below.

1. A method for generating a gene library from an environmental pool of organisms, which gene library is enriched in DNA encoding a polypeptide with an activity of interest, which method comprises:

subjecting the environmental pool of organisms to cultivation in a medium and/or under conditions suitable for enriching said pool of organisms in organisms harbouring said DNA; and

preparing a gene library from the resulting enriched pool of organisms.

12. The method of claim 1, wherein the environmental pool of organisms comprises microorganisms.

13. The method of claim 12, wherein the environmental pool of organisms comprises enzyme producing microorganisms.

14. The method of claim 12, wherein the microorganisms comprise Eubacteria, Archaeobacteria,

fungi, algae and protozoa.

Thus, the instant application is entitled to priority date of US Provisional application (60/106,319) and Danish priority application (1998 01388) and Okuta et al. is not prior art under 35 U.S.C. 102(b).

Notwithstanding that Okuta et al is not prior art to the claimed invention under 102(b), Okuta et al. also does not anticipate the claimed invention. The claimed invention is directed to a method for generating a gene library from an environmental pool comprising microorganisms, which gene library is enriched in DNA encoding a polypeptide with an activity of interest, which method comprises:

a) subjecting the environmental pool comprising microorganisms to cultivation under conditions wherein the pool comprising microorganisms is enriched in microorganisms harbouring said DNA, thereby forming an enriched environmental pool comprising microorganisms, and

b) preparing a gene library from the enriched environmental pool comprising microorganisms, wherein prior to said preparing there is no further purification of the enriched environmental pool of microorganisms.

Okuta et al. discloses a method to isolate functional hybrid C23O genes without isolating bacteria. In Okuta et al., bacteria from an environmental sample are grown on phenol or crude oil to enrich the bacteria in C23O. Fragments of the C23O genes are then isolated from the environmental sample by PCR using generate primers, and the genes fragments are used to construct functional hybrid genes. In Okuta et al., the library comprises only a library of C23O genes, prepared by obtaining "information concerning conserved amino acid sequences in a protein family form which degenerate primers are designed." See Okuta et al. at page 226, second column.

Okuta et al. does not, however, teach the preparation of a "gene library," as required by the present claim. As is well known in the art, a gene library represents the entire genome or expressed genes of an organism. The library prepared by Okuta et al is not the "gene library" of the claims. Indeed, in Okuta et al., the library comprises only a specific type of genes obtained using degenerate primer pairs directed to the specific genes.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

**V. The Rejection of Claims 4, 7, 10-11 and 18-19 under 35 U.S.C. 103(a)**

Claims 4, 7, 10-11 and 18-19 are rejected under 35 U.S.C. 103(a) as unpatentable over Okuta et al. in view of Sarka et al. This rejection is respectfully traversed.

As previously discussed, Okuta et al. is not prior art to the claimed invention under 102(b). In addition, Okuta et al. does not teach preparation of a "gene library," but rather it teaches preparing a library of C230 genes.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VI. Double Patenting**

Claims 1-20 are rejected for obviousness-type double patenting over claims 1-23 of U.S. Patent No. 6,723,504. Applicants respectfully submit a terminal disclaimer obviating this rejection.

For the foregoing reasons, Applicants submit that the claims overcome this rejection. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VII. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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